IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	)	C.A. No. 05-356 (KAJ)
	)	(consolidated)

REPLY IN SUPPORT OF DEFENDANT MYLAN'S RULE 12(c) MOTION FOR JUDGMENT ON THE PLEADINGS DISMISSING PLAINTIFFS' WILLFUL INFRINGEMENT CLAIM OR, IN THE ALTERNATIVE, TO BIFURCATE AND STAY DISCOVERY ON SUCH CLAIM

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I. INTRODUCTION

Janssen's opposition fails to address the primary issue before this Court: Whether Janssen may assert a claim for willful infringement in this Hatch-Waxman litigation based on the filing of an ANDA by Mylan. Under controlling law that Janssen does not – and cannot – seriously contest, the answer unequivocally is "no."

The Federal Circuit decided this very issue in *Glaxo*, explicitly holding that "the mere fact that a company has filed an ANDA application or [paragraph IV] certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)." *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350-51 (Fed. Cir. 2004). District courts subsequently addressing this same issue have left no room for doubt as how *Glaxo* should be applied – each having stricken or dismissed a willful infringement claim based solely on the filing of a drug application containing a paragraph IV certification. *See Allergan, Inc. v. Alcon Inc.*, No. 04-968 (GMS) (D. Del. July 26, 2005) (Sleet, J.) (Mylan Ex. A)[1]; *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, No. 04-1689 (D.N.J. Apr. 18, 2005) (Chesler, J.) (Mylan Ex. F); *Aventis Pharma Deutschland GmbH v. Cobalt Pharms., Inc.*, 355 F. Supp. 2d 586 (D. Mass. 2005) (Tauro, J.). Indeed, just a few days ago, another district court applied *Glaxo* to dismiss the plaintiffs' willful infringement claim where, like here, it rested solely on defendants' filing of an ANDA with a paragraph IV certification. *Aventis Pharma Deutschland GMBP v. Lupin Ltd.*, No. Civ.A. 2:05CV421, 2006 WL 141670 (E.D. Va. Jan. 18, 2006) (Doumar, J.) ("*Lupin*") (Ex. 1 hereto).

[1] "Mylan Ex." refers to the exhibits in the Compendium of Unreported Opinions Relating to Mylan's Rule 12(c) Motion, filed with Mylan's opening brief. (D.I. 59). "Janssen Ex." refers to the exhibits submitted by Janssen with its opposition to Mylan's motion. (D.I. 76).

Rather than address the relevant issue or law, Janssen makes legally irrelevant and inaccurate arguments. This Court should not be distracted by Janssen's tactics. Indeed, this Court can quickly dispense with Janssen's arguments. Applying the Federal Circuit's controlling holding in *Glaxo*, other courts already have considered and rejected the very arguments that Janssen makes here. This Court therefore should grant Mylan's motion and dismiss Janssen's claim for willful infringement.

In the alternative, Mylan seeks to bifurcate and stay discovery on Janssen's willfulness claim. Janssen not only glosses over Federal Circuit law on this issue – law which supports bifurcation in this Hatch-Waxman case – but entirely ignores recent decisions from this District demonstrating not only that bifurcation and a stay of discovery are permissible in such a case, but that such relief now is common. As such, in the event the Court denies Mylan's motion to dismiss Janssen's claim for willful infringement, the Court nonetheless should grant Mylan this alternative relief, and bifurcate and stay discovery on Janssen's meritless willful infringement claim.

II. ARGUMENT

A. Under Controlling Federal Circuit Precedent, Janssen May Not, As a Matter of Law, Assert a Claim For Willful Infringement in This ANDA Case.

1. The Federal Circuit's holding in *Glaxo* compels dismissal of Janssen's willfulness claim in this ANDA case.

Mylan's motion does not present an issue of first impression. The Federal Circuit expressly has held that patentees, like Janssen, cannot as a matter of law base a willful patent infringement claim on the filing of a paragraph IV ANDA:

> Consequently, as suggested by *Yamanouchi*, we now hold that the mere fact that a company has filed an *ANDA application or certification* cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4).

Glaxo, 376 F.3d at 1350-51 (emphasis added). Because 35 U.S.C. § 271(e)(2) –the provision under which Janssen sued Mylan here – solely "is designed to create an *artificial* act of infringement for purposes of establishing jurisdiction in the federal courts," the Federal Circuit held that the district court "committed clear legal error" by "hanging a finding of willfulness on such a special-purpose peg." *Id.* at 1351.

In reaching this conclusion, the Federal Circuit emphasized that even a "baseless" or "unjustified" paragraph IV certification or ANDA filing does not constitute willful infringement. *See Glaxo*, 376 F.3d at 1350. While such alleged conduct may be relevant to an "exceptional case" finding *after the litigation is complete*, it cannot elevate this "artificial act of infringement" – that serves a "very limited and technical purpose" of creating jurisdiction – into a finding of willfulness. *Id.* at 1350-51. *Glaxo* makes perfect sense, of course, because an ANDA-filer has not made, used or sold the accused product yet and therefore has not actually infringed the patent – especially since all research and development of the generic drug cannot constitute infringement. *See* 35 U.S.C. § 271(e)(1); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 665 (1990); *see also Lupin*, 2006 WL 141670, at *7 (concluding that in light of the ANDA scheme, "it comes as no surprise to this Court that *Glaxo* restricts willful infringement claims supported solely by allegations of baseless ANDA applications").

The district courts in *Allergan*, *Ortho-McNeil*, and *Aventis* each applied *Glaxo* to strike and/or dismiss claims for willful infringement in ANDA cases identical to this one. *See Allergan*, No. 04-968 (GMS), at 3-4 (Mylan Ex. A); *Ortho-McNeil*, No. 04-1689, at 1 (Mylan Ex. F); *Aventis*, 355 F. Supp. 2d at 592-93. Indeed, in just the last few days yet another district court relied on *Glaxo* and *Aventis* to dismiss a plaintiffs' willful infringement claim which, like Janssen's claim here, rested on defendants' filing of an ANDA with a paragraph IV certification:

"Defendants are absolutely correct that *Glaxo*, the latest case on the subject by the Federal Circuit, squarely holds that a willful infringement claim may not be based solely on the filing of a baseless ANDA application." *Lupin*, 2006 WL 141670, at *7 & n.5, *8-*9 (Ex. 1 hereto).

Here, by its own admission, Janssen bases its claim for willful infringement solely on Mylan's filing of an ANDA with a paragraph IV certification. (*See* Janssen Opp'n at 1, 9). Therefore, the Court should dismiss Janssen's willful infringement claim consistent with these other decisions addressing the same circumstances. Nothing Janssen has said, or could say, warrants a different result.

2. Janssen's attempts to avoid dismissal necessarily fail, as each district court addressing this issue has concluded.

In opposing Mylan's motion, Janssen makes a variety of arguments. But courts addressing this precise issue already have considered and rejected each of those arguments. Those courts have held in plain, simple language that a paragraph IV certification, even if "baseless" or filed "without a reasonable basis," cannot support a claim for willful infringement as a matter of law. *See, e.g.*, *Allergan*, No. 04-968 (GMS), at 3-4 (Mylan Ex. A); *Lupin*, 2006 WL 141670, at *7 n.5, *8-*9 (Ex. 1 hereto); *Aventis*, 355 F. Supp. at 591.

a. Janssen misconstrues *Glaxo* and *Yamanouchi*, both of which foreclose a claim for willful infringement in an ANDA case.

Janssen accuses Mylan of misinterpreting *Glaxo* and half-heartedly argues that *Glaxo* does not preclude a claim for willful infringement in an ANDA case involving a patent certification. (Janssen Opp'n at 2, 6.) Simply put, Janssen is wrong. As each of the district courts addressing this issue after the Federal Circuit's *Glaxo* ruling has recognized, *Glaxo* held that it is clear legal error to base a claim for willful infringement on the "special-purpose peg" or "artificial act of infringement" arising out of the submission of an ANDA and paragraph IV

certification – even one that is alleged to be "baseless." *See Glaxo*, 376 F.3d at 1350-51. Janssen admittedly bases its claim for willful infringement on precisely the same conduct.

Janssen also incorrectly (and disingenuously) suggests that *Glaxo* precludes a willfulness claim only in those cases where an ANDA applicant did not file a patent certification. (*See* Janssen Opp'n at 6 (arguing that "the patent certification requirements triggering this case were simply not at issue in *Glaxo*")). But the Federal Circuit could not have been clearer, expressly stating that its holding applies when "a company has filed an *ANDA application or certification*." *Glaxo*, 376 F.3d at 1350 (emphasis added). Consequently, it is not surprising that the district courts in *Aventis* and *Ortho-McNeil* rejected this very same argument, holding that the Federal Circuit's reference to a "certification" is not "mere surplusage," *Aventis*, 355 F. Supp. at 592, but rather "gives a very clear and forceful direction to the district court as to how the Federal Circuit views this particular claim," 4/18/05 Oral Argument Tr. at 10, in *Ortho-McNeil*, No. 04-1689 (Mylan Ex. G). *See also Lupin*, 2006 WL 141670, at *6 (concluding that "[c]onsequently, after *Glaxo*, it appears to this Court that a district court may not 'elevate' an ANDA certification, *even if it is 'baseless,'* into a finding of willful infringement for the purposes of attorney's fees") (Ex. 1 hereto).

In further attempting to muddy the waters, Janssen argues that *Yamanouchi* authorizes a claim for willful infringement in an ANDA case. (Janssen Opp'n at 2, 6-7.) Wrong yet again. *Yamanouchi* did not involve a finding of willfulness. Rather, the Federal Circuit affirmed an "*exceptional case*" finding – *not* a willful infringement claim – based on "misconduct in filing a wholly unjustified ANDA certification and misconduct during the litigation that followed . . . ." *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed. Cir. 2000). In fact, the Federal Circuit specifically stated in *Yamanouchi* that

"the trial court need not have elevated that ANDA certification into a finding of willful infringement." *Id.* (citation omitted). As if this were not enough, the Federal Circuit confirmed in *Glaxo* that even allegedly baseless certifications and litigation misconduct do not constitute willful infringement:

> [In *Yamanouchi*,] *we did not agree that the generic company had engaged in willful infringement*, but rather determined that an award of attorney's fees was permitted because the generic had filed numerous baseless filings supporting its fruitless and meritless arguments, both in its case at trial and in its ANDA certification. Such unjustified litigation and misconduct has always justified a finding of an exceptional case.

Glaxo, 376 F.3d at 1350 (emphasis added). Thus, *Yamanouchi* merely stands for the unremarkable proposition that a prevailing party may seek an award of attorneys' fees at the conclusion of the litigation based on an "exceptional case." But as the Federal Circuit made clear in *Glaxo*, that does not mean that Janssen may assert a claim for willful infringement, which is foreclosed as a matter of law. To the contrary, *Glaxo* and *Yamanouchi* acknowledge that such conduct could be relevant to an "exceptional case" determination and request for attorneys' fees at the conclusion of the trial and litigation—but as discussed below, this is entirely different from a claim for willful infringement. *See also Lupin*, 2006 WL 141670, at *7 (recognizing that "given that the appellate court in *Glaxo* clarified *Yamanouchi* to emphasize that an ANDA certification should not be 'elevated' into a finding of willful infringement," and concluding that "looking at the facts found by the lower court in *Glaxo* only confirms this Court's view that even a baseless ANDA filing could not constitute an act of willful infringement . . . .") (Ex. 1 hereto).

b. Janssen confuses a claim for willful infringement with an "Exceptional Case" finding.

Janssen further suggests that, because attorneys' fees can be awarded in ANDA cases under 35 U.S.C. § 285 in an "exceptional case," a claim for willful infringement is

appropriate as well. (Janssen Opp'n at 7 & n.2, 8.) Again, not so. District courts already have considered and rejected Janssen's argument, which confuses a claim for willful infringement and a claim for attorneys' fees based on an "exceptional case" finding.

As in any patent case, *at the conclusion of the litigation*, the prevailing party (whether Mylan or Janssen here) may petition the Court for an award of attorneys' fees on the ground that the case is "exceptional." As the Federal Circuit acknowledged in *Glaxo* and *Yamanouchi,* things like "wholly unjustified" certifications and litigation misconduct during the case and at trial could be relevant to the "exceptional case" determination. *Glaxo*, 376 F.3d at 1350; *Yamanouchi*, 231 F.3d at 1346-47; *see also Allergan*, No. 04-968 (GMS), at 4 (citing *Glaxo* in holding that "a finding that a ANDA/paper NDA case is 'exceptional' can be based on meritless filings combined with litigation misconduct, *but a finding of willful infringement cannot*" (emphasis added)) (Mylan Ex. A). But this has nothing to do with a claim for willful infringement, which, as the *Glaxo* court recognized, has no place in an ANDA case where, as here, there has been no actual infringement to begin with. *See Glaxo,* 376 F.3d at 1350-51; *see also Lupin*, 2006 WL 141670, at *3, *7-*8 (stating that "the fact that the appellate court in *Glaxo* emphasizes that the purpose of the ANDA process is to create an 'artificial' act of infringement for jurisdictional purposes strongly supports this Court's conclusion that even a baseless ANDA filing may never constitute willful infringement").

Indeed, Mylan's present motion does not address Janssen's request for attorneys' fees based on allegations that this case is "exceptional," but rather seeks dismissal of Janssen's claim for willful infringement. While Mylan may one day file a dispositive motion on Janssen's "exceptional case" claim, that issue is entirely irrelevant to the present motion and is not before the Court. Simply put, it makes no difference whether or not Janssen is asserting a claim for

attorneys' fees based on an "exceptional case." Either way, Janssen may not assert a claim for willful infringement. The Court should not be misled by Janssen's attempt to cloud the relevant issue.

c. District courts have uniformly applied *Glaxo* to dismiss or strike claims for willful infringement in ANDA cases.

Janssen does not dispute that the district courts in *Allergan, Ortho-McNeil* and *Aventis* applied *Glaxo* to dismiss or strike claims for willful infringement, even in cases where allegedly "baseless" certifications were filed. Notably, another court even more recently struck the plaintiffs' willfulness claim from the complaint for the same reason. *See Lupin*, 2006 WL 141670 (Ex. 1 hereto).

In response, Janssen cites three cases and suggests that "this Court and other courts" have rejected the proposition that *Glaxo* precludes a willful infringement claim in ANDA cases involving paragraph IV certifications. (Janssen Opp'n at 8). Janssen conveniently, and disingenuously, omits the fact that two of the decisions involved discovery disputes, *not* dispositive motions to dismiss. *See Astrazeneca AB v. Andrx Pharms., LLC*, No. 04-80, at 2 (D. Del. Aug. 11, 2004) (Robinson, J.) (addressing "the issue of the documents relating to the parent patent") (Janssen Ex. A); *Wyeth Pharm. v. Teva Pharms. USA, Inc.*, No. 03-1293, at 163 (D.N.J. Aug. 5, 2004) (Shwartz, M.J.) ("evaluating a discovery dispute") (Janssen Ex. B). Even then, those courts acknowledged that such claims for willful infringement likely had no merit. *See Astrazeneca*, No. 04-80, at 2-3 (recognizing that based on *Glaxo*, "the mere filing of an ANDA is not, cannot be deemed willfulness," and stating that a motion to dismiss the willfulness claim may be appropriate if "the only factor that the plaintiff can prove in this case is the filing of the ANDA") (Janssen Ex. A); *Wyeth*, No. 03-1293, at 167 (recognizing that "just the ANDA filing,

without more, is not going to give you a finding of willfulness" and "a dispositive motion on this point may be appropriate at the appropriate time . . . .") (Janssen Ex. B).

The only other case on which Janssen relies for this proposition is *Novartis*. (Janssen Opp'n at 8 (citing *Novartis Pharms. Corp. v. Teva Pharms. USA, Inc.*, No. 05-CV-1887(DMC) (D.N.J. Dec. 30, 2005)). By conceding that *Novartis* involved "a motion to strike allegations related to 'exceptional' case status" for purposes of awarding attorneys' fees under 35 U.S.C. § 285, Janssen concedes the irrelevancy of this case. (*Id.*); *see also Novartis*, No. 05-CV-1887(DMC), at 2-4 (Janssen Ex. C). As discussed above, while a prevailing party may petition the Court for an award of attorneys' fees on the ground that the case is "exceptional," this has nothing to do with a claim for willful infringement as Janssen has asserted here. Thus, plainly, none of these cases supports Janssen's claim for willful infringement.

d. Janssen has failed to state a legally cognizable claim rendering its request for discovery irrelevant.

Janssen's final attempt to avoid the inevitable is a plea that this Court allow full discovery or trial prior to the Court deciding Mylan's motion. (Janssen Opp'n at 2, 9-10). This Court quickly can reject Janssen's baseless argument. The issue here is whether Janssen has pled a legally cognizable claim for willful infringement in this ANDA case, not whether Janssen can piece together enough evidence to support such a claim post-filing.

Janssen's willful infringement claim is based solely on Mylan's filing of an ANDA. Federal Circuit precedent, and district court decisions addressing the very circumstances presented here, prohibit such a claim. Thus, Mylan's motion is ripe for consideration and should be granted in light of binding Federal Circuit law. *See, e.g., Ortho-McNeil*, No. 04-1689, at 1 (granting defendants' motion for judgment on the pleadings dismissing plaintiff's claim of willfulness) (Mylan Ex. F); *Aventis*, 355 F. Supp. 2d at 592 (allowing defendant's motion for

judgment on the pleadings with respect to plaintiffs' claim of willful infringement); *see also Lupin*, 2006 WL 141670, at *1, *9 (granting defendants' motion for judgment on the pleadings under Rule 12(c) dismissing plaintiffs' willful infringement claim) (Ex. 1 hereto).

B. In The Alternative, Janssen's Willfulness Claim Should Be Bifurcated, and Discovery Stayed, Pending a Decision on Liability Because Such Relief Avoids Prejudice And Serves Judicial Economy.

Based on the prevalent Federal Circuit and district court decisions, the Court's consideration of Mylan's present motion should end with the dismissal of Janssen's willful infringement claim. Nonetheless, in the event the Court considers the alternative relief of bifurcation, Janssen provides this Court with no basis to deny Mylan's request. Indeed, Janssen fails to address any recent decision propounded by this Court on this issue, much less any decision that should undermine this Court's authority under Rule 42(b) to bifurcate and stay discovery on Janssen's willfulness claims here.

1. Only bifurcation and a stay of discovery here will avoid prejudicing Mylan and expedite resolution of this Hatch-Waxman case.

Under Rule 42(b), it is undisputed that this Court may order separate trials on distinct claims or issues to promote "convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy . . . ." FED. R. CIV. P. 42(b). In fact, Rule 42 "encourages" bifurcation "where experience has demonstrated its worth." FED. R. CIV. P. 42 advisory committee's notes.

Janssen does not seriously contest that bifurcation here will advance these very goals underlying Rule 42.[2] Nor can it be disputed that bifurcation and a stay of discovery in

[2] One of the few arguments Janssen advances on this point, *i.e.*, that "only some of the defendants in this case have sought bifurcation of willfulness," (Janssen Opp'n at 13), is incorrect, as all other defendants to this litigation have filed motions joining Mylan's current motion. (*See* D.I. 66-69, 75, 77). So it would not be "completely unworkable to bifurcate trial and discovery on willfulness" here, as Janssen contends. (Janssen Opp'n at 13).

Hatch-Waxman ANDA litigation, such as Janssen's suit here, is worthwhile given the statutorily-imposed duty of the parties to cooperate in expediting resolution of the litigation on the merits. *See, e.g., Eli Lilly & Co. v. Barr Labs., Inc.*, No. 1:02-CV-1844-SEB, slip op. (S.D. Ind. Mar. 31, 2004) (bifurcating and staying discovery on willfulness in an ANDA case) (Mylan Ex. M); *SmithKline Beecham Corp. v. Teva Pharms. USA, Inc.*, No. 02-3779(JWB), slip op. at 7-16 (D.N.J. Mar. 5, 2003) (same) (Mylan Ex. N); *Ortho-McNeil v. Teva Pharms. USA*, No. 02-2794(GEB), slip op. at 4-8 (D.N.J. Jan. 28, 2003) (same) (Mylan Ex. O); *Allergan Inc. v. Pharmacia Corp.*, No. Civ.A.01-141-SLR, 2002 WL 1268047, at *2 n.1 (D. Del. May 17, 2002) (Robinson, C.J.) (same) (Mylan Ex. B); *Pfizer Inc. v. Novopharm Ltd.*, 57 U.S.P.Q.2d 1442, 1445 (N.D. Ill. 2000) (same); *Eli Lilly & Co. v. Barr Labs., Inc.*, No. IP 96-0491-C-B/S, slip op. at 2-3 (S.D. Ind. Oct. 29, 1998) (same) (Mylan Ex. P); *Bayer AG v. Barr Labs., Inc.*, No. 92 Civ. 0381 (WK), slip op. at 1 (S.D.N.Y. Sept. 11, 1995) (same) (Mylan Ex. Q).

Significantly, Janssen completely glosses over the fact that the relief Mylan seeks is entirely consistent with the Federal Circuit's decision in *Quantam Corp. v. Tandon Corp.*, 940 F.2d 642 (Fed. Cir. 1991), upon which district courts routinely have relied to bifurcate willfulness from liability and stay such discovery. Since *Quantum*, district courts—including this District—confronted with an accused infringer facing a "*Quantum* dilemma" routinely have bifurcated and stayed discovery on willfulness claims pending resolution of liability. *See, e.g., Arthrocare Corp. v. Smith & Nephew, Inc.*, No. 01-504-SLR, slip op. at 3 (D. Del. Nov. 27, 2002) (Robinson, C.J.) (bifurcating and staying discovery on willfulness) (Mylan Ex. D); *St. Clair Intellectual Prop. Consultants, Inc. v. Sony Corp.*, No. Civ.A01-557-JJF, 2002 WL 1901268, at *2 (D. Del. Aug. 16, 2002) (Farnan, J.) (same) (Mylan Ex. C); *aaiPharma, Inc. v. Barr Labs., Inc.*, No. 7:01-CV-150-F1, slip op. at 2-3 (E.D.N.C. Sept. 9, 2002) (same) (Mylan

Ex. J); *Lear Corp. v. Bertrand Faure Technical Ctr., Inc.*, No. 00-CV-72895, slip op. at 12 (E.D. Mich. Sept. 4, 2001) (same) (Mylan Ex. K); *Novopharm Ltd. v. TorPharm, Inc.*, 181 F.R.D. 308, 312 (E.D.N.C. 1998) (same); *Princeton Biochemicals, Inc. v. Beckman Instruments, Inc.*, 180 F.R.D. 254, 260-61 (D.N.J. 1997) (same); *Thomcast, A.G. v. Cont'l Elecs. Corp.*, No. 94-G-2486-S, slip op. at 1-2 (N.D. Ala. Apr. 24, 1995) (same) (Mylan Ex. L); *In re Recombinant DNA Tech. Patent & Contract Litig.*, 30 U.S.P.Q.2d 1881, 1900-01 (S.D. Ind. 1994) (same); *Sage Prods., Inc. v. Devon Indus., Inc.*, No. 93-2403 RG(CTX), 1994 WL 791601, at *3 (C.D. Cal. Jan. 25, 1994) (same) (Mylan Ex. I); *B. Braun Med. Inc. v. Abbott Labs.*, 32 U.S.P.Q.2d 1211, 1215-16 (E.D. Pa. 1994) (same).

Janssen suggests that it should be irrelevant to the consideration of bifurcation that the movant faces a *Quantum* dilemma, *i.e.*, being forced to choose between waiving privilege and risking a willfulness finding. (Janssen Opp'n at 14). Janssen is seriously mistaken. This dilemma is the very issue to which the Federal Circuit spoke in *Quantum*, stressing that district courts should give "serious consideration" to bifurcating willfulness from liability to avoid forcing a defendant to pick between waiving privilege and risking a willfulness finding. *Quantum*, 940 F.2d at 643-44. Indeed, the Federal Circuit warns that:

> Proper resolution of [this] dilemma . . . is of great importance not only to the parties but to the fundamental values sought to be preserved by the attorney-client privilege. An accused infringer . . . should not, without the trial court's careful consideration, be forced to choose between waiving the privilege in order to protect itself from a willfulness finding, in which case it may risk prejudicing itself on the question of liability, and maintaining the privilege, in which case it may risk being found to be a willful infringer if liability is found.

Id.

Thus, the fact that Mylan faces the very prejudice about which the Federal Circuit warned in *Quantum* is entirely relevant to the Court's consideration here. Indeed, bifurcation of

willfulness from liability and a stay of discovery related to willfulness is the only way to prevent Mylan from facing this dilemma, and from suffering severe prejudice. On this basis alone, bifurcation and a stay of discovery are warranted.

Janssen also argues that bifurcation is "not to be routinely ordered," but fails to cite any authority to uphold this outcome under the circumstances presented to the Court in this litigation. Rather, in urging this Court to deny Mylan's alternative request, Janssen focuses on pre-*Quantum* decisions or other authority that either supports Mylan's motion or is otherwise readily distinguishable from the circumstances here.[3] (Janssen Opp'n at 10-14).

Further, and significantly, Janssen has not presented any argument as to how there will be any evidentiary overlap between liability and willfulness. (*See* Janssen Opp'n at 12-13). In fact, there will be none. As it stands now, the liability trial would focus on objective issues of patent validity. The proof needed to resolve liability is entirely different than the evidence needed for willfulness. The liability trial will focus on objective technical and factual issues concerning, for instance, what the relevant universe of prior art teaches. Should Janssen ultimately prevail on liability and go forward on willfulness that trial would focus exclusively on Mylan's state of mind at the time of the alleged infringement. Thus, the circumstances of this litigation weigh heavily in favor of bifurcating and staying discovery on Janssen's willfulness claim. Nothing Janssen argues suggests a different result.

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[3] *Corrigan v. Methodist Hospital*, 160 F.R.D. 55 (E.D. Pa. 1995) did not address a willful infringement claim, but rather involved a medical malpractice action. (*See* Janssen Opp'n at 11.) In *Kos Pharmaceuticals, Inc. v. Barr Laboratories, Inc.*, 218 F.R.D. 387 (S.D.N.Y. 2003), the court refused to bifurcate where the dispute only involved two parties and, "[a]t issue . . . is *not one patent, as was the case in some of the instances in which courts have bifurcated willfulness from infringement*, but five patents, . . . significantly affecting Kos's prospects of prevailing as to some of its claims." *Kos*, 218 F.R.D. at 391, 393 (emphasis added). The reasoning supporting denial of bifurcation in *Kos* actually supports Mylan's motion here—a case involving seven (7) defendants and one patent.

2. Mylan's Bifurcation Request Is Timely.

Janssen argues that Mylan's motion is somehow "untimely." Janssen's argument lacks merit. First, Janssen asks this Court to impose a time requirement for filing a motion to bifurcate. Rule 42 itself, of course, does not impose such a requirement, nor has Janssen cited any authority to support the timing limitation it advances. This Court should reject Janssen's invitation to create new law here. Second, Janssen argues that the parties "are now far along in their discovery and other pretrial activities." (Janssen Opp'n at 15). This point not only is entirely irrelevant, it is untrue. The discovery to date has been limited to written discovery and document production, as Janssen currently is preventing Defendants from starting to take the depositions that they have noticed, and Janssen has not noticed any of its own depositions of Defendants (nor has Janssen commenced any of the "fair amount of foreign discovery" Janssen expressed to the Court over three months ago that it required, *see* D.I. 25, at 27). And obviously, as demonstrated by this pending motion, discovery on the issue of willfulness is nowhere near complete, as Janssen contends. (*See* Janssen Opp'n at 15). Therefore, Janssen's argument is tenuous, and disingenuous, at best.

Furthermore, Janssen's argument ignores the fact that this Court expressly stated that Defendants could move "at a later time" to bifurcate and stay willfulness. Specifically, the Court stated at the October 12, 2005 Scheduling Conference that the parties had the "opportunity or right to raise the [bifurcation] issue at a later time," (D.I. 25, at 16), and the Revised Scheduling Order that this Court just entered on January 12, 2006, reflects this right, (D.I. 81, ¶ 3 (indicating that "[t]he Court will not bifurcate and stay discovery on Plaintiffs' willful infringement claim at this time. This is without prejudice of any party raising dismissal and/or bifurcation at a later date.")).

Therefore, this Court should dismiss any suggestion by Janssen that Mylan's motion is untimely. For all the reasons set forth here and in Mylan's opening brief, bifurcation is warranted in the absence of a dismissal of plaintiffs' willful infringement claim.

III. CONCLUSION

The controlling law from the Federal Circuit, as applied now by at least four district courts, clearly precludes Janssen's claim for willful infringement in this case. The Court therefore should grant Mylan's Rule 12(c) motion for judgment on the pleadings and dismiss Janssen's claim for willful infringement. Alternatively, this Court should bifurcate, and stay discovery on, Janssen's willfulness claim in order to avoid prejudicing Mylan and to serve the interest of judicial economy in this Hatch-Waxman case.

Dated: January 24, 2006.

Respectfully submitted,

MYLAN PHARMACEUTICALS INC. and
MYLAN LABORATORIES INC.

By: *_/s/ Mary B. Matterer_*

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In re: '318 Patent Infringement Litigation,
C.A. No. 05-356 (KAJ) (consolidated) (D. Del.)

EXHIBIT 1
to Mylan's Reply in Support of Its Rule 12(c) Motion:

Aventis Pharma Deutschland GMBH v. Lupin Ltd.,
No. Civ.A. 2:05CV421, 2006 WL 141670
(E.D. Va. Jan. 18, 2006)

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Only the Westlaw citation is currently available.

United States District Court,
E.D. Virginia.
AVENTIS PHARMA DEUTSCHLAND GMBH and King Pharmaceuticals, Inc., Plaintiffs
v.
LUPIN LTD. and **Lupin** Pharmaceuticals, Inc.
Defendants.
No. Civ.A. 2:05CV421.

Jan. 18, 2006.

MEMORANDUM OPINION AND ORDER

DOUMAR, J.

***1** In this case, Plaintiffs Aventis Pharma Deutschland GMBH ("Aventis") and King Pharmaceuticals, Inc. ("King") have brought a two-count suit against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. for patent infringement and inducement of infringement. Presently before the Court is Defendants' motion for judgment on the pleadings under Fed.R.Civ.P. 12(c), asking this Court to dismiss Plaintiffs' willful infringement claim. For the reasons stated herein, Defendants' motion is GRANTED and the Court DISMISSES Plaintiffs' willful infringement claim WITHOUT PREJUDICE to the Court's ability to consider the "totality of circumstances" should the Court determine this is an "exceptional case" and fees are merited pursuant to 35 U.S.C. § 285 at the conclusion of this litigation.

I. Background

Plaintiff Aventis owns U.S. Patent No. 5,061,722, known as the " '722 patent." The '722 patent involves a pharmaceutical compound known as "ramipril" that is used to treat high blood pressure. Co-plaintiff King, the exclusive licensee of the '722 patent, markets ramipril under the trade name "ALTACE."

On March 18, 2005, Lupin Ltd., a generic drug company, submitted an "Abbreviated New Drug Application" ("ANDA") to the Food and Drug Administration (FDA) seeking approval to market generic versions of the ramipril capsules developed by Aventis. Pursuant to the ANDA content requirements established in 21 U.S.C. § 355(b) relating to the status of the "pioneer" patent, Lupin Ltd. certified that Plaintiffs' patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" under paragraph IV of the provision, which is commonly known as "paragraph IV certification." *See* § 355(b)(2)(A)(iv); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1352 (Fed.Cir.2003). As required by 21 U.S.C. § 355(j)(2)(B), Lupin Ltd. also sent a notification letter to Plaintiffs about its ANDA application on June 8, 2005.

After receiving the notification letter from Lupin Ltd., Plaintiffs subsequently filed suit in this Court on July 19, 2005. On August 29, 2005, Plaintiffs then filed an Amended Complaint containing two counts. With respect to Count 1, their patent infringement claim, Plaintiffs allege:

- Lupin's submission of its ANDA to obtain approval to engage in the commercial manufacture, use and sale of Lupin's Ramipril Capsules, prior to the expiration of the '722 patent , constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2). Pl.'s Am. Compl. ¶ 20.
- Unless enjoined by this Court, Lupin, upon FDA approval of Lupin's ANDA, will infringe the '722 patent by making, using, offering to sell, importing, and selling Lupin's Ramipril Capsules in the United States. *Id.* ¶ 21.
- Lupin had notice of the '722 patent at the time

of its infringement. Lupin's infringement has been, and continues to be, willful and deliberate. *Id.* ¶ 23.

***2** • Lupin's Paragraph IV Certification that, in Lupin's opinion, the '722 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use or sale of Lupin's Ramipril Capsules is baseless. *Id.* ¶ 24.

• This case is an exceptional one, and King and Aventis are entitled to an award of their reasonable attorney's fees under 35 U.S.C. § 285. *Id.* ¶ 25.

• Plaintiffs will be substantially and irreparably damaged and harmed if Lupin's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law. *Id.* ¶ 26.

With respect to Count 2, their inducing infringement claim, Plaintiffs allege "[u]pon information and belief, Lupin Pharmaceuticals, Inc. has infringed the '722 patent under 35 U.S.C. § 271(b) by actively inducing Lupin Ltd. to infringe the '722 patent ." *Id.* ¶ 28. Plaintiffs conclude their complaint by requesting the following relief:

1. A judgment declaring that Lupin has infringed, and that Lupin's making, using, selling, offering to sell or importing Lupin's Ramipril Capsules and/or its active ramipril ingredient will infringe the '722 patent;
2. A judgment ordering that the effective date of any FDA approval for Lupin to make, use or sell Lupin's Ramipril Capsules be no earlier than the date on which the '722 patent expires, and expiration of any FDA exclusivities relating to King's ALTACE® drug products;
3. A judgment permanently enjoining Lupin from making, using, selling, offering to sell, or importing Lupin's Ramipril Capsules and/or its active ramipril ingredient until after the expiration of the '722 patent and any FDA exclusivities relating to King's ALTACE® drug products;
4. If Lupin engages in the commercial manufacture, use, offer to sell, or sale of Lupin's Ramipril Capsules and/or its active ramipril ingredient prior to the expiration of the '722 patent , a judgment awarding [P]laintiffs damages resulting from such infringement, increased to treble the amount found assessed, together with interest;
5. Attorney's fees in this action pursuant to 35 U.S.C. § 285;
6. Costs and expenses in this action; and
7. Such further and other relief as this Court may deem just and proper.

Id. ¶¶ (A)-(G).

On December 13, 2005, Defendants filed the present Rule 12(c) motion for judgment on the pleadings dismissing Plaintiffs' willful infringement claim. Plaintiffs filed their Memorandum in Opposition on December 27, 2005. Plaintiffs replied on December 30, 2005. The motion is therefore ripe for judicial determination.

II. Discussion

A. Standard of Review

Judgment on the pleadings, as provided by Fed.R.Civ.P. 12(c), [FN1] "authorizes resolution of a matter where no genuine issues of material fact remain and the moving party is entitled to judgment as a matter of law." *Zeran v. America Online, Inc.*, 958 F.Supp. 1124, 1128 (E.D.Va.1997). When reviewing a Rule 12(c) dismissal, "the allegations in the complaint are construed favorably to the plaintiff." *Bruce v. Riddle*, 631 F.2d 272, 273- 74 (4th Cir.1980). "All reasonable inferences" are thus drawn in favor of the plaintiff, *Zeran*, 958 F.Supp. at 1128, and a court must "find beyond a doubt that the plaintiff could prove no set of facts in support of his claim which would entitle him to relief." *Bruce*, 631 F.2d at 274. Because a Rule 12(c) motion tests the sufficiency of a claim, it "does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." *United States v. 328 Pounds More or Less, of Wild American Ginseng*, 347 F.Supp.2d 241, 244 (W.D.N.C.2004) (quoting *Republican Party of North Carolina v. Martin*, 980 F.2d 943, 952 (4th Cir.1992) (internal brackets omitted)). Accordingly, in order for a defendant's Rule 12(c) motion to succeed, the plaintiff must be precluded from recovering on his claim as a matter of law even if the pleadings were taken as true and construed in a light most favorable to the plaintiff. *Zeran*, 958 F.Supp. at 1128.

> FN1. Fed.R.Civ.P. Rule 12(c), Motion for Judgment on the Pleadings, provides:
> After the pleadings are closed but within such time as not to delay the trial, any party may move for judgment on the pleadings. If, on a motion for judgment on the pleadings, matters outside the pleadings are presented to and not excluded by the court, the motion shall be treated as one for summary judgment and disposed of as provided in Rule 56, and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion by Rule 56.

B. Analysis

1. The Parties' Arguments

***3** In this case, Defendants argue that Plaintiffs' allegations cannot support a claim for willful infringement as a matter of law. Def.'s Mem. in Supp. of its Rule 12(c) Motion at 4. Citing paragraphs 20 and 23 of Plaintiff's Amended Complaint, Defendants maintain "Plaintiffs allege that Lupin Ltd. willfully infringes the '722 patent based solely on the filing of Lupin Ltd.'s ANDA and paragraph IV certification with the FDA" even though "the Federal Circuit ... has specifically ruled that such allegations cannot support a finding of willful infringement." *Id.* at 4. In Defendants' view, "the Amended Complaint simply contains no allegations that could support a finding of willful infringement." *Id.* at 5.

Plaintiffs respond by noting that their Amended Complaint alleges that Defendants' infringement was "willful and deliberate" in paragraph 23, that their paragraph IV certification is "baseless" in paragraph 24, and that the case is "an exceptional one" in paragraph 25. Pl.'s Mem. in Opp. to Def.'s Rule 12(c) Motion at 3. Contending that Defendants misapply *Glaxo Group, Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed.Cir.2004) and *Yamanouchi Pharm. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339 (Fed.Cir.2000), Plaintiffs urge that, because they have alleged more than willful infringement by alleging that the paragraph IV certification is "baseless" and that Defendants have acted deliberately and in bad faith, they are entitled to develop and prove these allegations at trial.

2. The Hatch-Waxman Act, Willful Infringement, and Exceptional Cases

The ANDA application procedure was created by Congress in 1984, under what is commonly known as the "Hatch-Waxman Act." *See* 21 U.S.C. § 355; *Warner-Lambert Co.*, 316 F.3d at 1352. The Act was a "compromise between two competing sets of interests: those of innovative drug manufacturers, who had seen their effective patent terms shortened by the testing and regulatory process; and those of generic drug manufacturers, whose entry into the market upon expiration of the innovator's patents had been delayed by similar regulatory requirements." *Id.* at 1358. The Act, and the ANDA application process it created, is thus designed to accomplish the following: 1) exempt generic drug manufacturers from infringement actions when researching and developing a generic version of a patented drug before the patent has expired, and 2) provide the innovative drug manufacturer the opportunity to protect its patent by allowing it to bring an infringement action pursuant to the generic company's ANDA filing to determine whether the generic drug, *if* marketed, would infringe the patent. *Id.*

To accomplish these goals, one primary purpose of the ANDA filing is to create a "highly artificial" act of infringement to allow for subject matter jurisdiction in a district court to resolve any disputes about infringement *before* the generic drug is sold. *Eli Lily and Co. v. Medtronic, Inc.*, 496 U.S. 661, 679 (1990). The purpose "is to permit patent holders to bring suit against generic companies despite the fact that the generic companies have not yet infringed the patents at issue." *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed.Cir.2004). Indeed, the "paragraph IV" certification at issue here, one of four possible required certifications under the statute, demonstrates the anticipatory nature of the dispute, as generic companies must certify in their ANDA application the patent "is invalid or *will not be*

infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *See* § 355(b)(2)(A)(iv) (emphasis added); *see also Warner-Lambert,* 316 F.3d at 1352. Accordingly, filing an ANDA application is not a willful act of infringement in and of itself precisely because the ultimate finding of infringement involves an analysis of whether the patent *will be infringed* if the drug is made or marketed--"the inquiries are hypothetical." *Id.* at 1365. The hypothetical nature of the suit is also why "[t]his highly artificial act of infringement gives rise to only a limited set of statutorily-defined consequences set forth in 35 U.S.C. § 271(e)(4)" if actual infringement is shown. *Id.*

***4** Under 35 U.S.C. § 271(e)(4), the remedies available to a plaintiff that successfully protects its patent in ANDA cases are:

> (A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,
>
> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and
>
> (C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.
>
> The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

Section 285, which applies to all patent infringement cases generally, provides that "[t]he court in *exceptional* cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285 (emphasis added). When assessing whether a case is "exceptional," courts "must look at the totality of the circumstances." *Yamanouchi,* 231 F.3d at 1347. An ordinary case is certainly not "exceptional." Examples of "exceptional cases" for which the United States Court of Appeals for the Federal Circuit has awarded fees in typical patent infringement claims include "inequitable conduct before the PTO, litigation misconduct such as vexatious or unjustified litigation or frivolous filings, and willful infringement." *Glaxo,* 376 F.3d at 1350 (citing *Hoffman-La Roche Inc. v. Invamed Inc.,* 213 F.3d 1359, 1365 (Fed.Cir.2000); *Rosemount, Inc. v. Beckman Instruments, Inc.,* 727 F.2d 1540, 1548 (Fed.Cir.1984)).

At this point, when and how a court may award attorney's fees in exceptional cases involving a willful infringement allegation may seem straightforward. It is not. Both parties cite *Glaxo* and *Yamanouchi,* but, of course, interpret and apply them differently. Because *Glaxo* explains *Yamanouchi,* the Court will examine *Glaxo* and its analysis of *Yamanouchi* in detail.

a. The *Glaxo* Opinions

In *Glaxo,* the Court of Appeals for the Federal Circuit reversed the district court's finding that the generic company's ANDA filing constituted willful infringement because the "mere filing of an ANDA cannot constitute grounds for a willful infringement determination." *Id.* at 1342. Unfortunately, to understand the scope of the appellate court's opinion and what "mere filing" might mean, one must look at the district court's opinion in the case in order to appreciate the case's specific facts.

i) The District Court's Glaxo *Opinion*

***5** The district court in *Glaxo* concluded that Apotex, the generic company, had willfully infringed because "Apotex's ANDA filing [was] permeated by a lack of due care" and the "non-credible trial testimony of Apotex's witnesses are classic examples of conduct that clearly and convincingly demonstrates willfulness." *Glaxo Group Ltd. v. Apotex, Inc.,* 268 F.Supp.2d 1013, 1033, 1034 (N.D.Ill.2003). The district court first found that the CEO of Apotex, a Dr. Sherman, "never obtained an opinion of independent patent

counsel on either non-infringement or invalidity in this case" and relied only on the "hearsay declaration of a hired expert witness" to justify the ANDA filing. *Id.* The district court found that filing an ANDA "without any legal analysis of [drug's] patent rights" to demonstrate a lack of due care. *Id.* at 1034.

The district court also observed that, "[f]aced with [the] admission of infringement in the application he drafted, Dr. Sherman labeled his statement a 'typographical error." ' *Id.* The district court went on to point out that "[t]his attempt to evade as 'errors' or 'mistakes' ... was also the centerpiece of the testimony of another Apotex witness." Moreover, the person actually responsible for the statements, a Dr. Cappuccino, "disavowed any responsibility for the statements and characterized them as unauthorized," which the district court found to be not credible. *Id.* Finally, the district court described yet another witness, a Dr. Siegel, who "found the 'typographical error' to be a convenient explanation." *Id.* In the district court's view, these instances of non-credible testimony exemplified conduct that demonstrates willfulness. *Id.*

In addition, the district court was not persuaded by Apotex's argument that it did not act willfully because it did not provide a written certification when its ANDA was filed. The district court concluded its discussion by finding "the filing of the ANDA by Apotex triggered GlaxoSmithKline's infringement claim and constituted willful infringement in view of the circumstances described above." *Id.* at 1035 (emphasis added).

ii) The Court of Appeals for the Federal Circuit's Glaxo *Opinion*

The Court of Appeals for the Federal Circuit disagreed with the lower court's finding of willful infringement in *Glaxo. Glaxo,* 376 F.3d at 1349. It began its analysis by observing that filing an ANDA "constitutes a 'highly artificial' act of infringement." *Id.* It then explained the remedies available when a patent owner successfully shows infringement in the ANDA context, noting that attorney's fees may be awarded in exceptional cases. *Id.* at 1350. The appellate court went on to give willful infringement as an example of conduct constituting an "exceptional case" for the purposes of attorney's fees.

In addition to providing this example, however, the Court of Appeals for the Federal Circuit went on to explain it has "limited what types of conduct may give rise to an award of attorney's fees for the purposes [of the ANDA remedies in Section 271(e)(4)]." *Id* . It then discussed *Yamanouchi,* where it "determined that a baseless and 'wholly unjustified' paragraph IV certification in an ANDA filing, which combined with litigation misconduct, warranted an exceptional case finding" but *not* a "willful infringement finding." *Id.* (emphasis added). While baseless ANDA filings, meritless arguments, and litigation misconduct may constitute an exceptional case finding for the purposes of attorney's fees, the Court of Appeals for the Federal Circuit squarely held that "the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for the purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)." *Id.*

***6** While the *Glaxo* holding is straightforward, the extent of its application is not, because the facts surrounding Apotex's conduct are not included in the appellate opinion. Reading the text alone, the fact that the *Glaxo* court used the word "mere" to describe the act of filing an ANDA application suggests that any action beyond "mere filing" is not included in its standard. Something more than "mere" is usually something different. Thus the following question inevitably arises: could conduct *beyond* the "mere fact of filing an ANDA" support a finding of willful infringement for the purposes of attorney's fees?

As part of its rationale, the Court of Appeals for the Federal Circuit in *Glaxo* observed that the district court "did not find that Apotex engaged in any litigation misconduct, and Apotex did not file of paragraph IV certification of any kind, let alone one that made baseless accusations of invalidity such as that filed in *Yamanouchi."* [FN2] *Id.* With respect to *Yamanouchi,* the *Glaxo* Court then observed that

"the generic had filed numerous baseless filings supporting its fruitless and meritless arguments, both in is case at trial and in its ANDA certification." *Id.* Accordingly, the *Glaxo* court explained, they determined in *Yamanouchi* that "a baseless and 'wholly unjustified' paragraph IV certification in an ANDA filing, when combined with litigation misconduct, warranted an exceptional case finding." *Id.* at 1350. In this way, while the *Glaxo* court disagreed with the district court's "elevat[ion] of the ANDA certification into a finding of willful infringement," it also observed that the generic company's baseless ANDA certification accompanied by litigation misconduct appropriately resulted in an award of attorney's fees. *Id.* Consequently, after *Glaxo,* it appears to this Court that a district court may not "elevate" an ANDA certification, ***even if it is "baseless,"*** into a finding of willful infringement for the purposes of attorney's fees; rather, a baseless ANDA certification accompanied by litigation misconduct may result in an award of attorney's fees because such conduct constitutes an "exceptional case." *Aventis Pharma Deutschland GMBH v. Cobalt Pharm.,* 355 F.Supp.2d 586, 591 (D.Mass.2005).

> FN2. Isn't every failed ANDA filing essentially baseless? As discussed *infra,* the Court is inclined to think so, which is why the *Glaxo* court appears to have been so concerned about limiting attorneys fees to only exceptional cases where a "wholly unjustified" and baseless ANDA filing is also accompanied by litigation misconduct. *Glaxo Group Ltd. v. Apotex, Inc.,* 376 F.3d 1339, 1350 (Fed.Cir.2004).

Because *Glaxo* limited *Yamanouchi,* this Court suspects that the *Glaxo* court had the same concerns this Court had with the *Yamanouchi* decision. In *Yamanouchi,* the Court of Appeals for the Federal Circuit affirmed the lower court's decision to award attorneys fees as part of the "totality of circumstances" analysis for exceptional cases. It noted that the Defendants relied on a "legal opinion contain[ing] an acknowledged error in chemistry" and thus found that Defendants' ANDA filing lacked adequate foundation. *Yamanouchi,* 231 F.3d at 1347. The appellate court, unfortunately, did not include facts found in the lower court that mitigates what seems at first blush, to this Court at any rate, a harsh conclusion, as generally parties may rely on their lawyers' opinion as long as that reliance is reasonable and they adhere to the analysis in good faith. *See Central Soya Co., Inc. v. Geo. A. Hormel & Co.,* 723 F.2d 1573, 1577 (Fed.Cir.1983). The lower court's opinion in *Yamanouchi,* however, reveals that the lawyer who issued the opinion had a financial interest in the success of the ANDA application, as he would receive as a fee for his opinion "fifty percent of the 'Marginal Gross Profit' of any of the drugs' sales if its corresponding patent challenge was successful." [FN3] *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc.,* 21 F.Supp.2d 366, 375 (S.D.N.Y.1998). Given this lawyer's lack of objectivity and obvious bias, which the client was indeed very much involved, the appellate court's affirmation of the exceptional case finding becomes more clear. [FN4]

> FN3. The old adage "look for the money" is often a useful way to understand such conduct.

> FN4. This Court has already seen similar types of problems of this nature with some lawyers. *See X-It Products, LLC v. Walter Kidde Portable Equipment, Inc.,* 227 F.Supp.2d 494, 547 (E.D.Va.2002).

*7 With these egregious facts in mind, and given that the appellate court in *Glaxo* clarified *Yamanouchi* to emphasize that an ANDA certification should not be "elevated" into a finding of willful infringement, looking at the facts found by the lower court in *Glaxo* only confirms this Court's view that even a baseless ANDA filing could not constitute an act of willful infringement, although a baseless ANDA filing could constitute an exceptional case. As described *supra,* the district court found that the generic company filed what turned out to be a baseless ANDA "without any legal analysis of [drug's] patent rights." *Glaxo,* 268 F.Supp.2d at 1034. The district court also found the generic company's witnesses to not be credible. *Id.* at 1035. Yet the Court of Appeals for the Federal

Circuit reversed the willful infringement finding. This strongly suggests that the "mere" filing standard protects a lot of willful conduct indeed surrounding the filing of an ANDA and therefore excludes willful infringement allegations in connection with the ANDA.

Moreover, the fact that the appellate court in *Glaxo* emphasizes that the purpose of the ANDA process is to create an "artificial" act of infringement for jurisdictional purposes strongly supports this Court's conclusion that even a baseless ANDA filing may never constitute willful infringement. This is so because, as *Glaxo* explains, the purpose of the ANDA filing "is to permit patent holders to bring suit against generic companies *despite the fact that the generic companies have not yet infringed the patents at issue." Glaxo,* 376 F.3d at 1351 (emphasis added). If a generic company has not yet infringed the patent at issue because its infringement in filing an ANDA is only "technical" and "artificial" infringement for jurisdictional purposes, and if the resulting suit is a "hypothetical" one to determine *if* there would be infringement *if* the drug was marketed, *Warner-Lambert,* 316 F.3d at 1365, how could a patent holder accuse the generic company of willful infringement at all in the ANDA context if they can't allege a baseless ANDA filing? The Court is not sure how one could do it. [FN5] Indeed, as discussed *infra,* Plaintiffs' own facts demonstrate they are unable to bring a willful infringement claim unconnected to Defendants' filing of a baseless ANDA.

> FN5. *Glaxo* certainly suggests it is possible, as it gives willful infringement as one of its examples of instances where attorney's fees have properly been awarded. *Id.* at 1350. *Glaxo* appears, however, to be describing exceptional cases in patent law generally when it provides that example, and the lion's share of the opinion consists of a discussion of why the exceptional case analysis as opposed to willful infringement claims are appropriate in ANDA claims. In any event, as discussed *infra,* even if such an allegation is possible, Plaintiffs' have not alleged facts beyond the filing of a baseless ANDA, which *Glaxo* prohibits.

Finally, the Court is compelled to observe that, given its understanding of the ANDA scheme, excluding allegations of willful infringement based solely on the filing of a baseless ANDA application serves the purposes of the scheme itself, which is clearly to encourage generic companies to participate in the ANDA process so that consumers may benefit from the faster availability of generic drugs. Ultimately, any generic company who loses its patent infringement suit after filing a paragraph IV certification has filed a "baseless" ANDA application. Indeed, it appears to this Court that its entire inquiry in this case will be grounded on the ANDA and whether or not Defendants are correct that the patent is invalid and/or will not be infringed. Thus it comes as no surprise to this Court that *Glaxo* restricts willful infringement claims supported solely by allegations of baseless ANDA applications. While this is so, generic companies may not file baseless ANDA applications with impunity. The *Glaxo* court is at pains to point out that particularly egregious conduct surrounding the filing of the ANDA and in the litigation itself could warrant attorneys fees as an exceptional case, and it uses *Yamanouchi* as an example. *Glaxo,* 376 F.3d at 1350-51. Should the Court find such conduct in this case, it will accordingly utilize the exceptional case analysis provided for by the statute and discussed in *Glaxo.*

b. Plaintiffs' Facts

***8** While the Court has doubts that a patent holder may allege willful infringement at all in ANDA cases given the nature of the ANDA scheme, Plaintiffs' own pleading defeats the claim because all they allege is that Defendants willfully and deliberately filed a baseless ANDA. Plaintiffs allege Defendants infringed the '722 by filing an ANDA application. Am. Compl. ¶ 20. Plaintiffs then allege Defendants "had notice of the '722 patent at the time of its infringement. [Defendants'] infringement has been, and continues to be, willful and deliberate." *Id.* ¶ 23. Plaintiffs go on to assert that Defendants' "Paragraph IV Certification, that in

[its] opinion, the '722 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use or sale of [Defendants;] Ramipril Capsules is baseless." *Id.* ¶ 24. In this way, Plaintiffs' willful infringement claim rests, just as Defendants' contend, on the allegation that Defendants' willfully and deliberately filed a baseless ANDA application. This is exactly what *Glaxo* prohibits.

In *Aventis Pharma Deutschland GMBH v. Cobalt Pharm,* 355 F.Supp.2d 586 (D.Mass.2005), a district court reached this same conclusion under facts identical to facts before the Court here. In *Cobalt Pharm,* Plaintiffs alleged that the generic company willfully infringed the patent by "filing an 'utterly baseless' paragraph IV certification with the FDA." 355 F.Supp.2d 586 (D.Mass.2005) (quoting plaintiff's amended complaint). Cobalt, like Defendants here, filed a Rule 12(c) Motion asking that the willful infringement claim be dismissed. Relying on *Glaxo,* the district court granted Cobalt's motion, noting that "the only act of infringement alleged in Plaintiffs' amended complaint is Cobalt's filing of an ANDA and a paragraph IV certification with the FDA." *Id.* at 592. "Because this artificial act of infringement cannot be considered willful," the district court went on to explain, "Plaintiffs have averred no facts that can support a finding of willful patent infringement." *Id.* The same situation exists in this case. Defendants' Rule 12(c) motion to dismiss Plaintiffs' willful infringement claim is therefore GRANTED without prejudice to the Court later determining if this is a case is an exceptional one warranting a willful infringement determination based on the "totality of circumstances" and awarding attorney's fees.

c. Exceptional Cases

While it is clear from *Glaxo* that a willful infringement claim may not rest entirely on the "mere filing" of an ANDA application, even if that application is baseless, it is also clear that willfully filing a baseless ANDA application may be considered "misconduct" as part of the "totality of the circumstances" should attorney's fees be awarded as an "exceptional case." *Glaxo,* 376 F.3d at 1350; *Yamanouchi,* 231 F.3d at 1346-47; *AstraZeneca Pharm. L.P.,* 2005 WL 2864666 at *28 . Under *Glaxo,* district courts may consider willfulness, as long as the allegation does not rest on the mere filing of an ANDA application, as part of the "totality of circumstances" analysis for the purposes of attorney's fees. *Glaxo,* 376 F.3d at 1350 . Even though the Court has dismissed Plaintiffs' willful infringement claim, the bottom line is that, should attorney's fees be merited in this case, the Court ADVISES the parties that this dismissal will not limit its ability to weigh the "totality of circumstances" should it find this case to be an "exceptional" one and attorney's fees merited. *See Yamanouchi,* 231 F.3d at 1347.

III. Conclusion

***9** The Court concludes by observing that, in many respects, both parties make reasonable arguments based on their interpretations and applications of *Glaxo* and *Yamanouchi.* The opinions are difficult to reconcile but not impossible. [FN6] As pointed out *supra,* in *Yamanouchi,* the relied-on attorney's opinion was anything but disinterested. Even so, the *Glaxo* court emphasized that *Yamanouchi'* s situation was an "exceptional case" and the district court should not have elevated the conduct surrounding the baseless ANDA application, which was based on the very interested and involved attorney's opinion, into a finding of willful infringement, but rather "... baseless filings supporting its fruitless and meritless arguments both in its case at trial an in its ANDA certification" merited exceptional circumstances. *Glaxo,* 376 F.3d at 1350. It is obvious that *Glaxo* intended to limit *Yamanouchi* because otherwise the expansion of *Yamanouchi* would eviscerate the ANDA process outlined in the statute. Unfortunately for Plaintiffs, Defendants are absolutely correct that *Glaxo,* the latest case on the subject by the Federal Circuit, squarely holds that a willful infringement claim may not be based solely on the filing of a baseless ANDA application. And that is all Plaintiffs have alleged. This Court will follow the latest case of the Federal Circuit. Accordingly, Defendants' Rule 12(c) motion to dismiss Plaintiffs' willful infringement claim is GRANTED WITHOUT

PREJUDICE to its ability to consider whether or not this is an exceptional case and attorney's fees are merited pursuant to 35 U.S.C. § 285 and what may be the "totality of circumstances."

> FN6. By utilizing the district courts' opinions in both *Glaxo* and *Yamanouchi*, we can begin to reconcile the two decisions. Because the opinions failed to fully set out the facts in relation to the imposition of attorney's fees in both cases, reviewing the district courts' opinions in those cases makes the appellate court's results at least understandable.

The Clerk is DIRECTED to send a copy of this Memorandum Opinion and Order to all counsel of record by mail and facsimile.

IT IS SO ORDERED.

Slip Copy, 2006 WL 141670 (E.D.Va.)

END OF DOCUMENT

CERTIFICATE OF SERVICE

I hereby certify that on the 24th day of January, 2006, I electronically filed the foregoing document, **REPLY IN SUPPORT OF DEFENDANT MYLAN'S RULE 12(c) MOTION FOR JUDGMENT ON THE PLEADINGS DISMISSING PLAINTIFFS' WILLFUL INFRINGEMENT CLAIM OR, IN THE ALTERNATIVE, TO BIFURCATE AND STAY DISCOVERY ON SUCH CLAIM**, with the Clerk of the Court using CM/ECF, which will send notification to the following:

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